REMARKS

STATUS OF THE CLAIMS

Claims 1-5 and 7-9 were pending in the application. Claim 4 has been amended. Claim 6 was previously canceled. New claims 10-13 have been added. Claims 1-5 and 7-13 would be pending in the application if the instant amendment is entered.

Reconsideration and re-examination of this application in view of the above amendments and the following remarks is herein respectfully requested.

I. REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

Claims 4-5 were rejected in the present office action under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for reciting "... the compound is administered at a time point which is in the range defined to begin at a time point during the food intake ... ". The Office Action alleged that it was not clear what is meant by the above statement.

Applicant respectfully maintains that claim 4, as amended, and claim 5, which depends from claim 4, are sufficiently definite under 35 U.S.C. § 112, second paragraph. Claim 4 has been amended to recite "wherein the compound is administered within one hour after food intake is started." Accordingly, Applicant respectfully requests that the rejection under 35 U.S.C. § 112, second paragraph be withdrawn.

II. FIRST REJECTION UNDER 35 U.S.C. § 103(a)

Claims 1-5, and 7-9 have been rejected under 35 U.S.C. § 103(a) as being obvious over Biskobing (Expert Opinion Invest. Drug; of record) taken with WO 97/32574 (of record) in view of Halonen et al. (US 6,245,819; of record) further in view of Vasu, Council of Medical Research 2000 (newly applied). The Office Action alleged that Biskobing teaches administering ospemifene to treat bone loss but did not teach the treatment of skin atrophy. The Office Action also alleged that WO 97/32574 teaches that the claimed compounds can be taken with other active compounds, and that "food is can be [sic] active agent as it comprises nutrients for the functioning of the body." The Office Action further alleged that Halonen et al ('819 patent hereafter) disclosed FC127a(=deaminohydroxytoremifene) as well as active

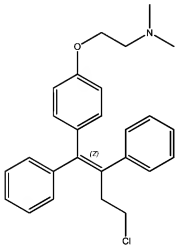
metabolites, geometric isomers or stereoisomers thereof (see col. 2 lines 35-59) for the treatment of vaginal dryness and sexual dysfunction (citing the Abstract).

Applicant respectfully maintains that claims 1-5 and 7-9 are not obvious under 35 U.S.C. § 103(a) over Biskobing, WO 97/32574, and the '819 patent, further in view of Vasu. Applicant does not concede there is a prima facie case of obviousness. Even assuming for the sake of argument that there is a prima facie case of obviousness, Applicant contends that there is sufficient rebuttal evidence to overcome the rejection.

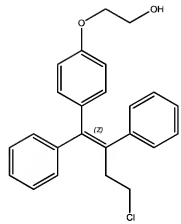
Teaching away

The USPTO must consider rebuttal evidence of teaching away. *See In re Sullivan*, 84 USPQ2d 1034, 1038 (Fed. Cir. 2007) (The Federal Circuit remanded an appeal back to the BPAI for failure to consider rebuttal evidence put forth by the Applicant during prosecution).

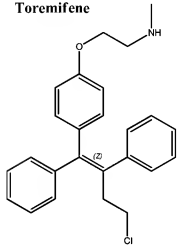
Here, Applicant wishes to draw the Examiner's attention to Anttila (1997) European J. Cancer 33 (Suppl. 8), 1144 ("Anttila") (previously cited in an IDS). Anttila discloses that toremifene "can be taken equally well in fasted conditions or with meals." The t_{max} (time to peak concentration) was delayed from 2.3 hours to 4.0 hours, but the C_{max} (peak concentration), AUC (area under the curve), and $t_{1/2}$ (half-life) values "were not significantly different" following a 14-hour fast compared to following a standard high-fat meal. In addition, the pharmacokinetic parameters for the active toremifene metabolite N-demethyltoremifene "were similar under fed and fasted conditions." Thus, Anttila would teach away from the presence of a food effect for triphenylethylenes such as ospemifene. The structures of toremifene, N-demethyltoremifene and ospemifene are reproduced below for the Examiner's convenience:



Toremifene



Ospemifene



N-demethyltoremifene

In accordance with *In re Sullivan*, Applicant respectfully requests that the teaching away of the Anttila reference be specifically addressed in the next Office Action or that a Notice of Allowance be issued.

Unexpected results

A patent applicant may also attempt to rebut a *prima facie* case of obviousness with evidence of suprising results. *See In re Peterson*, 315 F.3d 1325, 1330-1331 (Fed. Cir. 2003). To date, the USPTO has not acknowledged the unexpected results that are disclosed in the present application. The present application discloses that the effect of food intake on ospemifene absorption is 2-3 fold higher than in the fasted state (page 4, lines 4-5). The effect of food also increases the bioavailability of ospemifene in the fed state as compared to the fasted state. (see e.g., Figures 1 and 2). The Office Action, however, has not shown how one of skill in the art would expect

the surprising results shown in the specification. Applicant respectfully requests that the unexpected results be specifically addressed in the next Office Action or that a Notice of Allowance be issued.

Applicant respectfully maintains that claims 1-5 and 7-9 are not obvious under 35 U.S.C. § 103(a), and respectfully request that this rejection be withdrawn.

III. FIRST REJECTION FOR OBVIOUSNESS-TYPE DOUBLE PATENTING

Claims 1 and 8-9 remain rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-12 of U.S. Patent Application No. 11/201,098 (US 2005/0272825). The Office Action alleged that "[a]lthough the conflicting claims are not identical, they are not patentably distinct from each other because the claims require the compound ospemifene is administered for the treatment of skin atrophy. As evident by Vasu, drugs are known in the art to be administered, with food. With regard to Applicant's arguing that the disclosure is to enhancing bioavailability will not change treating atrophy, because as soon as the drug is available treating will proceed."

Applicant respectfully submits that claims 1 and 8-9 should not be rejected for obviousness-type double patenting over the '098 patent application. For the reasons set out above in response to the rejection under 35 U.S.C. § 103(a), Applicant similarly maintains that claims 1 and 8-9 should not be rejected for obviousness-type double patenting, in view of the teaching away of Anttila, and the unexpected results in disclosed in the specification. Therefore, Applicant respectfully requests that the obviousness-type double patenting rejection of claims 1, and 8-9 over US Application No. 11/201,098 be withdrawn.

IV. SECOND REJECTION FOR OBVIOUSNESS-TYPE DOUBLE PATENTING

Claims 1-9 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,984,665 ("the '665 patent"). The Office Action alleged that "[a]lthough the conflicting claims are not identical, they are not patentably distinct from each other. As evident [sic] by Vasu, drugs are known in the art to be administered with food."

Applicant respectfully submits that claims 1-9 should not be rejected for obviousness-type double patenting over the '665 patent. For the reasons set out above in response to the rejection under 35 U.S.C. § 103(a), Applicant similarly maintains that claims 1-9 should not be rejected for obviousness-type double patenting, in view of the teaching away of Anttila, and the unexpected results in disclosed in the specification. Therefore, Applicant respectfully requests that the obviousness-type double patenting rejection of claims 1-9 over the '665 patent be withdrawn.

CONCLUSION

In view of the foregoing, Applicant believes all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance is respectfully requested.

If the Examiner believes that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at 734-302-6010.

Respectfully submitted,

Dated: February 5, 2008

/Eric J. Baude/
Eric J. Baude
Reg. No.: 47,413
Attorney for Applicant(s)
(734) 302-6010